K131536

## 6. 510(k) Summary as Required by 21 CFR 807.92

**A. 510(k) Number:**

**B. Purpose for Submission:** New Device

**C. Measurand:** Quality Control materials for the IMMULITE® 2000 PSA assay

**D. Type of Test:** Calibration Verification Material (CVM) for IMMULITE® 2000 PSA assay

**E. Applicant:**

**1. Address:**
Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591

AUG 12 2013

**2. Contact Person:**
Garo Mimaryan, MS., RAC
Technical Regulatory Affairs Specialist III

**3. Phone Number:** (914)-524-3270

**F. Proprietary and Established Names:** IMMULITE® 2000 PSA Calibration Verification Material

**G. Regulatory Information:**

**1. Regulation Section:** 21 CFR 862.1660, Quality Control Material

**2. Classification:** Class I Reserved

**3. Products Codes:** JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)

**4. Panel:** Clinical Chemistry (75)

**H. Intended Use:**

**1. Intended Use(s):** See Indications for Use below.

**2. Indications for Use:** The IMMULITE® 2000 PSA Calibration Verification Material (CVM) is intended for monitoring system performance of the IMMULITE Immunoassay System for the quantitative measurement of PSA antigen.

**3. Special Conditions for Use Statement(s).** For prescription use only.

**4. Special Instrument Requirements:** IMMULITE® 2000 Systems

**I. Device Description:** The Calibration Verification Material (CVM) contains one set of four vials, 3 mL each. LPTSCVM1 contains processed chicken serum matrix with preservative. LPTSCVM2, LPTSCVM3 and LPTSCVM4 contain low, intermediate and high levels of PSA respectively, in processed chicken serum/buffer matrix with preservative.

**J. Substantial Equivalence Information:**

1. **Predicate Device Name:** Access Hybritech p2PSA QC
2. **Predicate 510(k) No.** k112603
3. **Comparison with Predicate:** A comparison of the device features, intended use, and other information demonstrates that the IMMULITE® 2000 PSA Calibration Verification Material (CVM) is substantially equivalent to the predicate device, Access Hybritech p2PSA QC, as summarized in the following table.

| REAGENT SIMILARITIES and DIFFERENCES | | |
|---|---|---|
| | **Candidate Device**<br><br>**IMMULITE 2000 PSA CVM** | **Predicate Device**<br><br>**Access Hybritech p2PSA QC** |
| **Intended Use** | The IMMULITE® 2000 PSA Calibration Verification Material (CVM) is intended for monitoring system performance of the IMMULITE Immunoassay system for the quantitative measurement of PSA antigen. | The Access Hybritech PSA QC are tri-level controls intended for monitoring system performance of immunoenzymatic procedures for the quantitative measurement of [-2]pro PSA isoform of Prostate Specific Antigen (PSA) using the Access Immunoassay Systems. |
| **Analyte** | PSA | [-2]proPSA isoform of Prostate Specific Antigen (PSA) |
| **Form** | Liquid | Same |
| **Stability** | Stable until the expiration date when stored frozen. | Same |
| **Storage** | -20°C | -20°C |
| **Matrix** | Processed (pH-treated) Chicken Serum | Bovine Serum Albumin and buffering salts |
| **Use** | Single Use Only | Not for Single Use |

**K. Standard/Guidance Documents Referenced:**

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

**L. Test Principle:**

Not Applicable

## M. Performance Characteristics

1. Analytical Performance:
   a. *Precision/Reproducibility:* Not Applicable
   b. *Linearity/assay Reportable Range:* Not Applicable
   c. *Traceability, Stability, Expected Values (controls, calibrators, methods):*

Traceability:
The IMMULITE PSA Calibration Verification Materials are traceable to WHO 1st International Standard 96/670.The CVMs are manufactured using approved reference lot manufactured with qualified materials and measurement procedures.

Stability:
The IMMULITE® 2000 Third Generation Calibration Verification Materials are stable up to 60 days when stored frozen at -20°C prior to opening. Unopened stability is indicated by expiration date on the label when stored at -20°C.

Value Assignment:
The 8-level Calibrators are for internal use only and not available for commercial use. Calibrators are used during product release of PSA assay. Calibrators are manufactured and values assigned using a stored curve generated with internal Gold Standards. Gold Standards are anchored to WHO international standard NIBSC 96/670. The 4-level CVM module is a subset of calibrators intended for use by customers to monitor system performance. The PSA CVMs can be run periodically as unknowns in PSA assay by the customer to monitor system performance.

The IMMULITE Calibration Verification Materials (CVMs) are value assigned using assigned reference calibrators. The assigned reference calibrators are prepared using PSA antigen stock and are traceable to WHO 1st International Standard 96/670. The CVMs are manufactured using qualified materials and measurement procedures. The CVMs were tested on 27 replicates in total comprised of nine runs, six instruments and five different reagent kit lots. The CVMs dose values are generated using curve generated by assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. The CVM values are then averaged across all systems. Quality control is performed by calculating the recovery of patient samples, spiked patient samples, normal male samples and controls using the assigned values. The controls must fall within their target ranges.

Production lots of CVMs are value assigned against the Gold Standard using two reagent kit lots and on a minimum of three different instruments. Quality control is performed by calculating the recovery of patient sample panels and controls using the assigned calibrator and CVM values. The calibrator values are calculated based on the recovered values for each run independently. Three levels of commercially available controls, 30 patient samples consisting of 10 normal male patient samples, 10 spiked human serum samples and 10 PSA samples were used to validate CVM value assignments.

The spiking recovery of the IMMULITE® 2000 PSA Calibration Verification Material (CVM) was determined to investigate potential matrix effects from using processed (pH-treated) Chicken Serum. Siemens spiked three concentrations of purified PSA antigen into human serum and an evaluation lot comprised of chicken serum. The PSA values of the evaluation lot were compared to the human serum lots. The acceptance criteria were 100% ±15% with an overall average of ±10%. Each of the samples met the acceptance criteria, and Siemens concluded that there were no matrix effects.

*d. Detection limit:* Not Applicable
*e. Analytical Specificity:* Not Applicable
*f. Assay cut-off:* Not Applicable

2. Comparison Studies
   a. *Method Comparison with predicate device:* Not Applicable
   b. *Matrix Comparison:* Not Applicable
3. Clinical Studies:
   a. *Clinical Sensitivity and Specificity:* Not Applicable
   b. *Other clinical supportive data (when a. and b. are not applicable):* Not Applicable
4. Clinical Cut-off: Not Applicable

5. Expected Values/Reference Range:
Each CVM level was tested on 5 different kit lots, 6 instruments, 9 runs for a total of 27 replicates. The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD). The expected values are provided in the IMMULITE® 2000 PSA Calibration verification Material lot-specific value sheet. The expected assay range is 0.08 - 150 ng/mL. The values below can be considered as guidelines.

| **Analyte target levels** | **Level** | **Target Mean (ng/mL)** | **SD** | **Guideline (ng/mL)** | |
|---|---|---|---|---|---|
| | 1 | 0.00 | | ≤0.085 | |
| | 2 | 1.44 | 0.08 | 1.28 | 1.60 |
| | 3 | 49.0 | 2.45 | 44.1 | 53.9 |
| | 4 | 169 | | Not Applicable | |
| | 152 (90% of 169 +10% of 0.00) | 152 | 7.5 | 137 | 167 |
| **Assay Range** | 0.08 - 150 ng/mL | | | | |

Expected Values:
Each laboratory should establish their limits for acceptability based on methodology, clinical significance and medical decision levels of the test analyte. The representative, total precision tabulated in the respective assay instructions for use may be considered as one factor when establishing local, acceptable ranges. The values provided above may be considered as guidelines. Value assignment is lot specific.

**N. Proposed Labeling:**
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

**O. Conclusion:** The IMMULITE® 2000 PSA Calibration Verification Material is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Access Hybritech p2PSA QC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 12, 2013

SIEMENS HEALTHCARE DIAGNOSTICS, INC
C/O MR. GARO MIMARYAN
REGULATORY AFFAIRS SPECIALIST III
511 BENEDICT AVENUE
TARRYTOWN, NY 10591

Re: K131536
Trade/Device Name: IMMULITE® 2000 PSA Calibration Verification Material
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: I
Product Code: JJX
Dated: May 28, 2013
Received: May 29, 2013

Dear Mr. Mimaryan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K131536

**Device Name:** IMMULITE® 2000 PSA Calibration Verification Material

**Indication for Use:**

The IMMULITE® 2000 PSA Calibration Verification Material (CVM) is intended for monitoring system performance of the IMMULITE Immunoassay system for the quantitative measurement of PSA antigen.

Prescription Use X And/Or Over the Counter Use_____

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Maria M. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k131536